83-1925

No._____

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT
v.
AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE ELEVENTH CIRCUIT

JURISDICTIONAL STATEMENT

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60 pp

QUESTION PRESENTED

Whether Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder regulating collection of blood plasma from paid donors are preempted by the federal regulatory scheme establishing standards and procedures for plasmapheresis operations.

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OPINIONS BELOW

The opinion (App. B, pp. A-13 - A-19) and final judgment (App. C, p. A-20) of the United States District Court for the Middle District of Florida, William J. Castagna, J., are not reported. The opinion of the United States Court of Appeals for the Eleventh Circuit (App. A, pp. A-1 - A-12) is reported at 722 F.2d 1526.

JURISDICTION

The judgment of the United States Court of Appeals for the Eleventh Circuit (App. D, p. A-21) declaring that Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations are preempted by the federal scheme regulating plasma and, therefore, invalid was entered on January 16, 1984. A Petition for Rehearing By Panel was filed by Hillsborough County, Florida on February 4, 1984 (App. E, pp. A-22 - A-25). The Eleventh Circuit Court of Appeals entered an Order denying the Petition for Rehearing on February 23, 1984. (App. F, p. A-26). A Notice of Appeal to the United States Supreme Court (App. G, pp. A-27 - A-28) was filed by Hillsborough County, Florida in the United States Court of Appeals for the Eleventh Circuit on April 20, 1984. The jurisdiction of this Court is invoked under 28 *U.S.C.* §1254(2), which provides for a direct appeal to the United States Supreme Court from a decision of a federal court holding a state statute to be unconstitutional. The United States Supreme Court has held that, for purposes of invoking the jurisdiction of the United States Supreme Court under 28 *U.S.C.* §1254(2), local ordinances are treated as state statutes, *City of New Orleans v. Dukes*, 427 U.S. 297, 96 S.Ct. 2513 (1976); *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 95 S.Ct. 2561 (1975); *City of Chicago v. Atchison, Topeka and Santa Fe Railway Co.*, 357 U.S. 77, 78 S.Ct. 1063 (1958).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The citations for the constitutional provisions, statutes, ordinances and regulations involved in this case are as follows:

United States Constitution, Article 6, Clause 2, states that:

> Clause 2. Supreme Law of Land
> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 C.F.R. 600.3 - 680.26 (1983)

Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder. The pertinent texts of these ordinances and regulations are set forth in the Appendix. (App. H, pp. A-29 - A-42).

STATEMENT OF THE CASE

Automated Medical Laboratories, Inc. ("AML"), which operates a plasma collection center known as Tampa Plasma Center ("TPC") in Hillsborough County, Florida, filed a twelve-count complaint in the U.S. Court for the Middle District of Florida against Hillsborough County, Florida ("County") and the Hillsborough County Health Department challenging the constitutionality of Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations. (App. F, p. A-26). The first count alleged that the federal government had preempted the area of plasma collection by issuing the regulations contained in 21 C.F.R. 600.3 - 680.26 (1983). Following a non-jury trial, United States District Court Judge William J. Castagna rejected all of AML's constitutional attacks on the local legislation, including AML's federal preemption attack, except for the claim that §7 of Ordinance 80-12 and §4 of the rules

and regulations imposed an impermissable burden on interstate commerce. (App. B, pp. A-13 - A-19).

AML appealed the Judgment of the District Court upholding the validity of the local legislation to the Eleventh Circuit. The County cross-appealed that portion of the Judgment which held that §7 of Ordinance 80-12 and §4 of the rules and regulations were invalid.

In its appeal to the Eleventh Circuit, AML challenged the purpose and necessity of the local legislation, the cost of compliance with it, and whether it imposed an impermissable burden on interstate commerce. The County's cross-appeal dealt with whether those two sections which were held invalid by the District Court in fact constituted an impermissable burden on interstate commerce.

Neither party raised the issue of federal preemption in the appeal. In fact, the preemption issue was raised only by the *amicus curiae* brief of the American Blood Resources Association ("ABRA") and the Florida Association of Plasmapheresis Establishment ("FAPE") which was filed by leave of court subsequent to the submission of the County's Answer Brief. Although the County specifically requested the opportunity to respond to the new issues raised by the *amicus* brief in its Motion for Rehearing or Clarification of the Court's Order granting leave for ABRA/FAPE to file an untimely *amicus* brief (App. I, pp. A-43 - A-46), that opportunity was denied by the Court in its Order filed on August 2, 1983. (App. J, p. A-47). The Court entered that Order even though Fed. R. App. p. 29 provides as follows: "Save as all parties otherwise consent, any *amicus curiae* shall file its brief within the time allowed the party whose position as to affirmance or reversal the *amicus* brief will support *unless the Court for cause shown shall grant leave for later filing, in which event it shall specify within what time an opposing party may answer*". (Emphasis supplied).

In its Opinion (App. A, pp. A-1 - A-12) entered on January 16, 1984, the Eleventh Circuit Court of Appeals held that,

though no express preemption existed, the County ordinances and regulations were implicitly preempted by federal regulation, as the pervasiveness of the federal regulatory scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, that the federal interest in plasmapheresis was dominant over any local interest, and that the enforcement of state law would present a serious danger of conflict with the administration of the federal program. Thus, the Eleventh Circuit Court declined to reach any of the other issues raised on appeal. Further, the Court failed to address the point raised by Hillsborough County in its cross-appeal. Accordingly, the District Court's judgment finding Section 7 of Ordinance 80-12 and Section 4 of the County rules and regulations invalid was affirmed, and the judgment finding the remaining sections of the County ordinances and rules and regulations valid was reversed by the Eleventh Circuit Court of Appeals.

STATEMENT OF THE REASONS WHY THE QUESTION PRESENTED IS SUBSTANTIAL

The question presented as to whether the federal regulatory scheme implicitly preempted the area of regulation of plasma collection is a substantial one because it not only affects the ability of Hillsborough County to enact such legislation for the protection of the health, safety and welfare of its local residents, but would also preclude other state and local governments within the jurisdiction of the Eleventh Circuit Court of Appeals from enacting legislation to regulate plasma collection in their areas. The decision by the Eleventh Circuit Court of Appeals that the area of plasma regulations has been implicitly preempted by the federal government due to the pervasiveness of the federal regulatory scheme constitutes an intrusion into an area of peculiarly local concern — the public health, safety and welfare. Such an intrusion into the police powers of a local government is unwarranted absent a clear intention to preempt. Where there is no explicit preemption provision in legislation passed by the federal government which allegedly conflicts with state legislation, preemption will not be presumed. *New York State Department of Social Services v. Dublino*, 413 U.S. 405 (1973). Absent an express preemption or express conflict be-

tween state and federal legislation, the legislation must be examined to determine whether they can coexist. Federal and local enactments should as a rule be accommodated and the law does not favor the ouster of local legislation. *Merrill, Lynch, Pierce, Fenner & Smith, Inc. v. Ware*, 414 U.S. 117 (1973).

Hillsborough County enacted Ordinances 80-11 and 80-12 and their companion rules and regulations while fully cognizant of the comprehensive federal regulations in the area of plasma collection. In fact, Hillsborough County expressly incorporated the federal regulations appearing at 21 C.F.R. Part 640, Subpart G, Section 640.60 *et seq*, the provisions of the federal regulatory scheme relating solely to "Source Plasma (Human)". Nevertheless, Hillsborough County went beyond the federal requirements in order to protect its residents against the dangers of cross-bleeding and of unnecessary contamination of plasma centers by hepatitus - positive plasma vendors as well as to ensure that paid donnors were capable of understanding the risks involved in the plasmapheresis process and of giving their informed consent to undergo that process. In addition, Hillsborough County provided for local inspection of plasma centers to supplement the only minimal federal inspection process. In fact, substantial evidence was presented at trial by experts in the field of plasmapheresis as well as by representatives of the federal Food and Drug Administration that Hillsborough County's plasma ordinances and regulations would be valuable supplements as to the federal regulatory scheme and would not adversely affect the national blood policy.

Just as Hillsborough County has perceived a need for local legislation regulating plasma collection, many other localities have recognized similar needs in their communities.[1] thus, the question of whether the federal regulatory scheme has preempted the area of plasma legislation is a substantial issue and worthy of this Court's consideration.

Respectfully submitted,

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[1] The records of the federal Department of Biologics indicate plasma regulation in the following state and local governments: Dade County, Florida; California; Connecticut; Illinois; City of New Orleans; Michigan; New Jersey; New York; Ohio; Puerto Rico; Tennessee; Virginia; State of Florida; Georgia; Maryland; and Pennsylvania.

CERTIFICATE OF SERVICE

All parties required to be served have been served by depositing on this 23rd day of May, 1984 copies of this document in a U.S. Post Office, with first class postage prepaid, addressed to counsel of record at his or her post office address as follows:

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APPENDIX

722 FEDERAL REPORTER, 2d SERIES

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,
v.
HILLSBOROUGH COUNTY, Florida, and
Hillsborough County Health Department,
Defendants-Appellees.

No. 83-3014.

United States Court of Appeals,
Eleventh Circuit.

Jan. 16, 1984.

Appeal was taken from a judgment of the United States District Court for the Middle District of Florida, William J. Castagna, J., finding that parts of county ordinances regulating collection of blood plasma from paid donors by plasmapheresis were invalid. The Court of Appeals, Tuttle, Senior Circuit Judge, held that ordinances were implicitly preempted by federal regulation, as pervasiveness of federal regulatory scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, federal interest in plasmapheresis was dominant over any local interest, and enforcement of state law would present serious danger of conflict with administration of federal program.

Affirmed in part, reversed in part.

1. States 4.10
Preemption of state law by federal statute or regulation is not favored in the absence of persuasive reasons. U.S.C.A. Const. Art. 6, cl. 2.

2. States 4.10
Touchstone of a preemption analysis is congressional intent, which may be either express or implied. U.S.C.A. Const. Art, 6, cl. 2.

3. Counties 21½
Health and Environment 33
States 4.12
County ordinances regulating collection of blood plasma from paid donors by plasmapheresis were implicitly preempted by federal regulation, as pervasiveness of federal regulatory

scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, federal interest in plasmapheresis was dominant over any local interest, and enforcement of state law would present serious danger of conflict with administration of federal program. U.S.C.A. Const. Art. 6, cl. 2; Public Health Service Act, §§ 2 et seq., 351, 42 U.S.C.A. §§ 201 et seq., 262; Federal Food, Drug, and Cosmetic Act, §§ 1 et seq., 201(g)(1), 21 U.S.C.A. §§ 301 et seq., 321(g)(1).

Larry A. Stumpf, Miami, Fla., for plaintiff-appellant.

Richard Landfield, Washington, D.C., for amicus Blood Resources Assoc. & FL Assoc. of Plasmapheresis Establishments.

Deolores D. Menendez and Emeline L. Acton, Tampa, Fla., for defendants-appellees.

Appeal from the United States District Court for the Middle District of Florida.

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

TUTTLE, Senior Circuit Judge:

Appellant Automated Medical Laboratories, Inc. ("Automated") filed a civil action against appellees Hillsborough County, Florida (the "County") and Hillsborough County Health Department (the "Department") in the United States District Court for the Middle District of Florida. Appellant challenged the constitutionality of County Ordinances 80-11 and 80-12 ("County Ordinances") and the rules and regulations promulgated thereunder. Following a nonjury trial, United States District Court Judge William J. Castagna rejected all of Automated's constitutional attacks on the local legislation, including its federal preemption attack, except for the claim that § 7 of Ordinance 80-12 and § 4 of the rules and regulations imposed an impermissible burden on interstate commerce. This Court finds that the County Ordinances are pre-empted by federal regulation. Therefore, the district court holding that § 7 of Ordinance 80-12 and § 4 of the rules and regulations are invalid is affirmed, and the holding that the remainder of the County Ordinances are valid is reversed.

I. BACKGROUND

Automated is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States. One of the centers, Tampa Plasma Corporation ("TPC"), is located in Tampa, Hillsborough County, Florida. Automated's plasma centers collect blood plasma from paid donors by plasmapheresis. Plasmapheresis is a process whereby, during a single procedure, blood is removed from a human donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor. Automated sells the plasma to pharmaceutical concerns, which use it in the manufacture of pharmaceutical products such as tetanus vaccine, albumin, and anti-hemophilic factor.

Prior to the enactment of the County Ordinances, the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") had issued regulations, which are contained in 21 C.F.R. §§ 600.3-680.26 (1983) (the "federal regulations"), that established standards and procedures for plasmapheresis operations. The federal regulations provide for FDA inspection of plasmapheresis facilities, establish standards for personnel and physical plants, necessitate licenses for plasmapheresis products and facilities, and establish human blood product standards, including the means to select suitable plasmapheresis donors.

In conformance with the federal regulations, TPC selects plasma donors on the basis of medical history, tests, and physical examinations. On each potential donor's initial visit, and at four-month intervals thereafter, TPC's staff physician reviews the candidate's medical history, performs a physical examination, and decides whether to reject or accept the candidate. If the candidate is accepted, the physician explains the plasmapheresis procedure as well as its associated risks and obtains the candidate's written informed consent to having the plasmapheresis procedure performed. In addition to the regularly scheduled staff physician's review and examination, nonmedical employees of TPC, who are trained and supervised by the staff physician, review the candidate's medical history prior to each donation of plasma. Nonmedical employees also determine, prior to each donation of plasma, that the candidate's weight, body temperature, blood pressure, pulse rate, serum protein, and hematocrit value are within the limits established by the federal regulations.

In conformance with the federal regulations, TPC has established procedures for eliminating from its donor population persons whose plasma could contain hepatitis virus. The staff physician rejects any candidate who has a history of viral hepatitis, a history of addiction to self-injected narcotics, or who has, within the preceding six months, had close contact with anyone having viral hepatitis, undergone major surgery, received whole blood or any human blood derivative known to be a possible source of viral hepatitis, or been tattooed. In addition, TPC sends a sample of each donation of plasma it collects to an outside laboratory operated by another wholly owned subsidiary of Automated to be tested for hepatitis contamination. If a sample is found to be contaminated, TPC destroys the unit of plasma from which the sample was taken and permanently rejects the donor from whom that unit was collected.

TPC has also established procedures for eliminating candidates who have exceeded the volume and frequency limits for plasma donations established in the federal regulations. To monitor the frequency with which a person donates plasma, TPC has established a donor identification system. At the time of a donor's first visit, TPC requires two forms of identification to establish the donor's identity. To identify the donor on subsequent visits, TPC provides the donor with an identification card, to which is affixed the donor's photograph. In addition, TPC establishes for each donor a permanent donor record file, which contains the donor's photograph and signature, as well as descriptive identifying information (address, telephone number, birthday, sex, height, eye and hair color, race, and blood type), written reports of the donor's physical examinations, signed consent forms, and written records documenting every plasma donation made. For each donation, TPC documents the date of donation, the bleed number, the donor's medical history and laboratory test results, and the volume of whole blood and red blood cells returned. By means of a permanent donor record file, TPC can deter any attempted donation which would result in a potential donor subjecting his or her health to risks by exceeding the amount and frequency limits set forth in the federal regulations.

TPC is not required by the federal regulations to coordinate its donor identification system with that of other plasma centers in the County. If, however, circumstances warrant the checking of a potential donor's identity with another plasmapheresis center, TPC's phlebotomists examine both arms of the potential

donor for signs of recent needle marks. Any potential donor who evidences recent needle marks that cannot be attributed to previous donations reflected in his or her permanent donor record file is referred to the staff physician for further evaluation.

The federal regulations provide for the inspection of TPC by an FDA official at least once every two years. The FDA inspection covers all aspects of the condition of TPC's facility, equipment, and records, as well as the methods used by TPC in collecting, processing, testing, storing, and shipping the plasma it collects. During the four years preceding the trial of this action, TPC was inspected approximately six times by the FDA. Those inspections apparently failed to reveal any deficiency in TPC's plasmapheresis operation other than a noisy fan or air conditioner in the staff physician's office, which allegedly made it difficult for one physician to communicate well with potential donors, forms that needed to be reprinted to make them clearly legible, and the observation, contested by TPC at the time of the inspection, that the staff physician had once "checked off" certain parts of a potential donor's physical examination form before actually performing them.

On November 26, 1980, the County adopted Ordinances 80-11 and 80-12. Ordinance 80-11 imposes a license tax and conditions the issuance of a license on, among other things, agreement by the blood plasma donor center to "reasonable and continuing access" by Department personnel for inspections, a public hearing, and continuously updated information regarding the owners, employees, equipment, and facilities.

The stated purpose of Ordinance 80-12 is "to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County." On March 5, 1981, the Department issued rules and regulations pursuant to Ordinance 80-12. Ordinance 80-12 requires that a potential donor must undergo a medical examination and obtain a "certificate of good health" before participating in the plasmapheresis process within the County. The regulations require that a potential donor present that certificate, together with his or her own sworn affidavit stating that he or she has not been detained or treated for acute or chronic alcoholism during the preceding twelve months, to the Department. The Department then issues its own identifica-

tion card to the potential donor. This identification card permits the potential donor to undergo plasmapheresis for a period of six months only at a single specified plasmapheresis facility located within the County.

Ordinance 80-12 also requires that TPC submit to the Department on a daily basis information as to each plasmapheresis procedure performed, including the following: the date of the procedure; the name, address, age, weight, height, sex, identification number, and current hematocrit value of the donor; the results of the donor's breath analysis; the amount of whole blood removed and the proportion of red cells returned; and the results of testing for hepatitis. Neither the ordinance nor the regulations indicate what use the Department is to make of this information. Ordinance 80-12 and the regulations also require TPC to pay the Department a fee of $1.00 for each plasmapheresis procedure it performs. The purpose of this fee seems to be limited to maintaining the bureaucracy needed to store the information provided by TPC.

Ordinance 80-12 authorizes the Department to inspect TPC periodically, even though the Department apparently employs no qualified inspector. The regulations provide that such inspections shall occur at least annually. Finally, Ordinance 80-12 subjects TPC to criminal sanctions for violation of its provisions.

II. DISCUSSION

The first issue before this Court is whether County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder are pre-empted by the federal scheme.

[1,2] The rationale underlying the pre-emption doctrine is that the Supremacy Clause invalidates state laws that "interfere with or are contrary to, the laws of congress...." *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824). Pre-emption of state law by federal statute or regulation is not favored in the absence of persuasive reasons. *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317, 101 S.Ct. 1124, 1130, 67 L.Ed.2d 258 (1981); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142, 83 S.Ct. 1210, 1217, 10 L.Ed.2d 248 (1963). The touchstone of a pre-emption analysis is congressional intent, which may be either express or implied. *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664, 675 (1982); *Jones v. Rath Packing Co.*, 430 U.S. 519, 529, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977); *Howard v. Uniroyal, Inc.*,

719 F.2d 1552 at 1555-56 (11th Cir. 1983). In *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. at 143, 83 S.Ct. at 1218, 10 L.Ed.2d 248, the Supreme Court stated a two-pronged analysis for pre-emption claims: "Does either the nature of the subject matter, ... or any explicit declaration of congressional design to displace state regulation, require [the challenged legislation] to yield to the federal [regulatory scheme]?" We must first examine the federal law for an explicit declaration of Congress's intent to pre-empt state law.

Blood and blood components are biological products subject to the Public Health Service Act, 42 U.S.C.A. § 262 (1982), and are drugs subject to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 321(g)(1) (1972). *See Blank v. United States*, 400 F.2d 302, 305-06 (5th Cir. 1968); *United States v. Calise*, 217 F.Supp. 705, 709 (S.D.N.Y. 1962). The Public Health Service Act establishes licensing and product standards and the Federal Food, Drug, and Cosmetic Act provides that unadulterated drugs may not be shipped in interstate commerce. Neither statute expressly precludes state action[1]. Nor do the applicable regulations explicitly dictate pre-emption[2]. *See* 21 C.F.R. §§ 600.3-680.26 (1983).

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[1] The attorney for the American Blood Resources Association and the Florida Association of Plasmapheresis Establishment, parties who appeared as amici curiae, argue that section 351 of the Public Health Service Act explicitly expresses Congress's intent to pre-empt state law. Section 351 provides in relevant part:

> (a) No person shall sell, barter or exchange, ... or send, carry or bring for sale, barter or exchange ... any ... blood, blood component or derivative ... unless (1) such ... blood, blood component, or derivative ... has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, ... (d) Licenses for the maintenance of establishments ... may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations .... All such licenses shall be issued, suspended, and revoked as prescribed by regulations....

42 U.S.C.A. § 262 (1982).

This Court does not find that the statute contains express language indicating pre-emption. *Cf., Armour and Company v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981, 93 S.Ct. 2267, 36 L.Ed.2d 957 (1973) (federal statute in question expressly provided that requirements in addition to, or different than, those made under the statute may not be imposed by any state).

[2] "Federal regulations have no less pre-emptive effect than federal statutes." *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982) (Supreme Court found preemption where the preamble accompanying the regulations unequivocally expressed intent to pre-empt conflicting state law). *Accord, United States v. Jones*, 707 F.2d 1334, 1336-37 (11th Cir. 1983).

[3] Having found no express intent to pre-empt state law, we next examine Congress's implicit intent in enacting the federal scheme. "Where Congress has not stated specifically whether a federal statute has occupied a field in which the states are otherwise free to legislate, different criteria have furnished touchstones for decision." *Pennsylvania v. Nelson*, 350 U.S. 497, 501-02, 76 S.Ct. 477, 479-80, 100 L.Ed. 640 (1956) (footnote omitted). *Accord Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1556 (11th Cir. 1983). Three tests are set out in *Pennsylvania v. Nelson* to determine if state law is implicitly pre-empted.

The first test is whether the federal scheme is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it. *Pennsylvania v. Nelson*, 350 U.S. at 502, 76 S.Ct. at 480, 100 L.Ed. 640. The federal scheme set out in the statutes and implementing regulations at issue here is comprehensive. The three basic requirements of section 351 of the Public Health Service Act ("Act") are that each establishment producing a biological product be licensed, each product be licensed based on standards designed to insure safety, purity, and potency, and that the package and labeling meet specified standards. 42 U.S.C.A. § 262 (1982). Within the federal regulations implementing the Act, 21 C.F.R. §§ 600.3-26 (1983)[3], one part deals specifically with "Source Plasma (Human)," which is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. 21 C.F.R. §§ 640.60-640.76 (1983)[4]. Other portions of

[3] Pursuant to Section 361 of the Act, 42 U.S. C.A. § 264 (1982), and under authority delegated to him, 21 C.F.R. § 5.10, the Commissioner of Food and Drugs is authorized to promulgate regulations. When an administrator promulgates regulations intended to pre-empt state law, the court will not disturb his efforts unless he has exceeded his statutory authority or acted arbitrarily. In examining pre-emption regulations, the court must ask whether the administrator intended to pre-empt state law, and if so, whether that action is within the scope of the administrator's delegated authority. *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. at 151, 102 S.Ct. at 3022, 73 L.Ed.2d 664. In this case, there is no contention that the regulations promulgated pursuant to the Act exceed statutory authority. It does not appear to the Court that the regulations extend beyond the authority granted by Congress.

[4] The regulations prescribe rules as to consent of a prospective donor, medical supervision of the procedure, suitability of donors, method of collection, requirements of the plasmapheresis procedure, immunization of donors, testing for hepatitis, processing of the blood, pooling, inspection, labeling, manufacturing responsibility, records, reporting of fatal donor reactions, modification of source plasma, alternate procedures, and products stored or shipped at unacceptable temperatures.

the regulations implementing the Act also apply to plasmapheresis[5].

The federal regulations are broad in scope and cover virtually every phase of the plasmapheresis process. The pervasiveness of the regulatory scheme makes it reasonable to infer that Congress left no roon for local ordinances to supplement it. *See Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1559 (11th Cir. 1983). Nevertheless, pre-emption is not to be inferred merely from the comprehensiveness of the federal scheme. *New York State Department of Social Services v. Dublino*, 413 U.S. 405, 415, 93 S.Ct. 2507, 2514, 37 L.Ed.2d 688 (1973).

The second test under *Pennsylvania v. Nelson* is whether the federal statute touches a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject. *Pennsylvania v. Nelson*, 350 U.S. at 504, 76 S.Ct. at 481, 100 L.Ed. 640. Congress has maintained extensive and comprehensive control over the nation's blood collection since 1946. 38 Fed.Reg. 2966 (1973). The collection of blood is an area of national concern, for "[h]uman blood is a priceless resource." 39 Fed.Reg. 18614 (1974). According to the Commissioner of Food and Drugs:

> The promulgation of standards for these biological drugs is part of an existing effort to increase the quality of blood related health care in this country. Pursuant to the findings of a special Task Force in Blood Banking, the Secretary of Health, Education, and Welfare has established a *comprehensive National Blood Policy*. One of the fundamental methods prescribed by the Secretary to implement the policy is to "employ the full regulatory authorities now vested in the Federal Government . . . for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."

[5] The subjects included within the remaining regulations are establishment standards and inspection, 21 C.F.R. §§ 600.3-22 (1983); licensing, 21 C.F.R. §§ 601.1-601.33 (1983); good manufacturing practices for blood and blood components, 21 C.F.R. §§ 606.3-606.170 (1983) (with specific sections relating to personnel, facilities, equipment, supplies and reagents, standard operating procedures, finished product and laboratory controls, labeling, records, and reports); establishment registration and product listing, 21 C.F.R. §§ 607.3-607.65 (1983); general biological products standards, 21 C.F.R. §§ 610.65 (1983) (including standards of potency, hepatitis requirements, dating periods, and labeling standards).

39 Fed.Reg. 18614 (1974) (emphasis added). *See also* 39 Fed.Reg. 18615 (1974) ("Such regulations are within the broad Congressional mandate to pursue the high remedial public health purpose of both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.") Furthermore, the Supreme Court has indicated that the Food, Drug, and Cosmetic Act should be given a liberal construction consistent with its overriding purpose to protect the public health. *See United States v. An Article of Drug ... Bacto-Unidisk ...*, 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1960); *United States v. Dotterweich*, 320 U.S. 277, 280, 64 S.Ct. 134, 136, 88 L.Ed. 48 (1943).

Although the County possesses an interest in the health of its residents, federal laws may still preclude enforcement of the County scheme. *See Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982) (pre-emption is not inapplicable simply because real property is a matter of special concern to the states). The regulations clearly express a federal interest in establishing a uniform "National Blood Policy." *Cf. Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143-44, 83 S.Ct. 1210, 1218, 10 L.Ed.2d 248 (1963) (the maturity of avocados is an inherently unlikely candidate for exclusive federal regulation). Therefore, we conclude that the federal interest in plasmapheresis is dominant over any local interest.

The third test in *Pennsylvania v. Nelson* is whether the enforcement of state law presents a serious danger of conflict with the administration of the federal program. 350 U.S. at 505, 76 S.Ct. at 482, 100 L.Ed. 640. The Commissioner of Food and Drugs described the purpose of the federal scheme as follows:

> To insure there is a continued healthy donor population to serve as a source of plasma to be used in the manufacture, by the fractionation technique, of safe, pure, and potent blood products, the Commissioner is including in these proposed additional standards for Source Plasma (Human) specific provisions designed to protect the health and well-being of the donor.

37 Fed.Reg. 17420 (1972). Thus, the regulations were designed to protect the plasma donors, to insure that the product is safe, and to insure the continued existence of a healthy donor population. *See also* 39 Fed.Reg. 26162 (1974); 39 Fed.Reg. 18615 (1974); 41 Fed.Reg. 10762-63 (1976). The regulations were also

enacted to establish uniform standards for blood banking. 39 Fed.Reg. 26161 (1974). The goal of uniformity runs throughout the regulations. *See, e.g.*, 48 Fed.Reg. 26313 (1983) (one reason for regulations establishing FDA inspection at least once every two years is to provide uniformity in the frequency of inspection).

The purpose of the County scheme is similar to that of the federal scheme. Section 15 of Ordinance 80-12 incorporates by reference the federal regulations appearing at 21 C.F.R. Part 640, Subpart G, Section 640.60 *et seq*. As noted earlier, these are the provisions of the federal regulatory scheme relating solely to "Source Plasma (Human)." The other provisions of the County Ordinances, however, impose additional requirements on plasmapheresis centers.[6]

These additional County requirements cover areas that are clearly encompassed by the federal regulations. Unlike *Smith v. Pingree*, 651 F.2d 1021, 1025 (5th Cir. 1981) (Unit B), in which the court found that the federal requirements did not regulate every aspect of the area and so the state had the implied reservation to fill out the scheme, the federal scheme here regulates every aspect of plasmapheresis. The County scheme imposes burdensome and expensive requirements in addition to the requirements of the comprehensive federal scheme. If the County scheme remains in effect, the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors will be adversely affected. *See Campbell v. Hussey*, 368 U.S. 297, 301, 82 S.Ct. 327, 329, 7 L.Ed.2d 299 (1961) (pre-emption found where act refers to need for uniform official standards); *Howard v. Uniroyal*, 719 F.2d 1552 at 1560 (11th Cir. 1983) (pre-emption found where one of Congress's objectives was to insure that there would be a uniform, consistent federal approach).

Thus, Automated has satisfied the three tests set out in *Pennsylvania v. Nelson*. This Court holds that Hillsborough Coun-

[6] The County scheme adds the following requirements: 1) A person may donate plasma only after obtaining a donor registration card, at a cost of $2.00, valid for six months at a single designated plasma center; 2) a donor registration card is issued only after the donor receives a complete physical exam and a hepatitis test and presents a sworn statement that within the preceding year, he or she has not been treated for chronic or acute alcoholism; 3) the plasma center must keep and forward daily to the Department records of the donors and procedures performed; 4) each donor must undergo a breath analysis prior to donation; 5) the Department shall inspect the plasma center at least once a year, and 6) the plasma center must pay the Department $1.00 for each plasmapheresis procedure performed.

ty Ordinances 80-11 and 80-12 and the implementing rules and regulations are pre-empted by the federal scheme. The Court need not reach any other issues raised on appeal. Accordingly, the judgment of the district court finding Section 7 of Ordinance 80-12 and § 4 of the rules and regulations invalid is AFFIRMED, the judgment finding the remaining sections of the County Ordinances and implementing rules and regulations valid is REVERSED.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 81-1161-Civ-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiffs,
vs.
HILLSBOROUGH COUNTY, FLORIDA, et al.,
Defendants.

FILED CLERK, U.S. DISTRICT COURT
NOV. 1, 1982
MIDDLE DISTRICT OF FLORIDA, TAMPA, FLORIDA

OPINION

This cause came on before the Court on a non-jury trial on September 16 and 17, 1982. Plaintiff Automated Medical Laboratories, Inc. filed this action against Hillsborough County, Florida and the Hillsborough County Health Department, challenging the constitutionality of Hillsborough County Ordinances 80-11 and 80-12 and the Rules and Regulations promulgated thereunder. The challenged ordinances regulate licensing and operation of paid blood plasma donor centers. Plaintiff sought a declaratory judgment that the ordinances were unlawful and a permanent injunction against enforcement of the legislation.

Plaintiff challenged the ordinances on several grounds. It claimed that federal legislation preempted the local laws, that the local ordinances impermissibly burdened interstate commerce, and that the county ordinances unlawfully deprived Plaintiff of equal protection of the law by regulating only plasma centers that pay donors and not centers where unpaid volunteers donate whole blood. Plaintiff raised several other issues in the pleadings, such as unlawful delegation, violation of rights, privileges and immunities, and violation of due process. Plaintiff did not specifically adduce evidence or address these issues at trial, however, and the Court finds these arguments without merit.

Based on the evidence presented at trial and a review of the exhibits, the Court makes the following findings:

(1) Plaintiff is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States, one of which, Tampa Plasma Corporation, is located in Tampa, Hillsborough County, Florida. Plaintiff's plasma centers collect blood plasma from paid donors by plasmapheresis. In a single procedure this process removes whole blood from the donor, removes the plasma from the whole blood, and then returns the red blood cells to the donor. Plaintiff sells the plasma collected to pharmaceutical concerns that manufacture it as a raw material into products such as tetanus vaccine, albumin, and anti-hemophilic factor. Tampa Plasma Corporation collects and sells no whole blood.

(2) When Hillsborough County enacted the challenged ordinances, the Food and Drug Administration of the United States Department of Health and Human Services had issued regulations in 21 C.F.R. Subchapter F - Biologics that established standards and procedures for plasmapheresis operations. The regulations provide for FDA inspection of plasmapheresis facilities, establish standards for personnel and physical plants, necessitate licenses for plasmapheresis products and facilities, and establish human blood product standards, including the means to select suitable plasmapheresis donors.

(3) Hillsborough County Ordinance 80-11 imposes a license fee on plasmapheresis centers. The purpose of Hillsborough County Ordinance 80-12 is "to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County." Pertinent provisions include the requirement that all plasma vendors obtain an identification card from the Health Department (at a cost of $2.00 as provided for in the rules and regulations pursuant to the ordinance). The ordinance requires the plasmapheresis centers to keep records of the procedures they perform, including the results of hepatitis testing, and to ascertain that a plasma vendor has not undergone a plasmapheresis procedure within specified time periods. The ordinance prohibits performance of the plasmapheresis procedure on any vendor who has not obtained a certificate of good health after examination by a physician. It imposes a fee, not to exceed $1.00, for each procedure performed, with a limitation that fees collected shall not exceed the cost of administering and maintaining the identification system. It requires a pre-plasmapheresis breath analysis of each vendor by means of approved equipment, material, and supplies. The ordinance incorporates

by reference the FDA regulations as they appear at 21 C.F.R., Subpart G, Section 640.60 et seq.

(4) In conformance with the FDA Regulations, Tampa Plasma Center currently provides its donors with identification cards. These cards are issued by individual centers, however, and plasma centers throughout the county do not cross-check with each other to ascertain whether a vendor has recently undergone plasmapheresis. The prospective vendor must give a medical history and undergo a physical examination, parts of which are performed by the center's non-medical personnel. A physician who has informed the vendor of the possible hazards and has questioned him about his understanding of the procedure accepts or rejects the vendor. After the plasmapheresis procedure is completed, a hepatitis test is performed and the plasma is kept in segregated storage until the center receives the results.

Under the county ordinances, the vendor would be required to obtain a county-wide identification card, which would not be issued prior to performance of a physical exam. The vendor would undergo a hepatitis test prior to registration, and breath analysis for alcohol content would be performed prior to each plasma donation.

(5) At trial, officers of the Plaintiff corporation attempted to establish the cost to Plaintiff of compliance with the ordinances. Their figures, however, were clouded with speculation. Mr. Dennis Healey, for instance, testified about a document he prepared (Exhibit 20) showing estimates of implementation costs. Except for the cost of the new fees, implemented by the Hillsborough County Health Department, the other estimated increased costs were based on Mr. Healey's opinion that the vendor population would decrease by twenty-five percent once the ordinances were enforced, primarily because the cost and inconvenience of obtaining the Health Department identification card would discourage new vendors. Mr. Healey, however, testified to no facts on which he based his opinion.

Plaintiff also encountered difficulty in estimating the increased cost per liter of plasma attributable to the requirement that the plasmapheresis center determine a prospective vendor's blood alcohol content by use of breathalyzer equipment manned by personnel with approved training. Plaintiff estimated that the machine alone would cost about $5,000.00; however, personnel training costs could not be estimated because approved training

presently is available only through the Tampa Police Department.

(6) Much of the testimony at trial concerned the intent of the County Commissioners in enacting the ordinances. Plaintiff attempted to demonstrate that the ordinances were enacted in response to the social problems caused by inebriates and vagrants frequenting the area around the plasma centers. Plaintiff argued that the purpose of the regulations was to eliminate plasmapheresis centers from Hillsborough County by imposing severe economic burdens on their operations. Plaintiff failed to prove, however, that the legislative intent was anything other than that articulated in Ordinance 80-12 — to register and to identify vendors and to supplement and extend the federal regulations and their purposes.

(7) Defendants introduced testimony from physicians qualified as experts in the plasmapheresis field as to the need for and beneficial effect of a county-wide system of vendor identification. Under the federal regulations no system monitors the frequency with which individual vendors undergo the plasmapheresis procedure. Because of monetary inducements for undergoing plasmapheresis, vendors may donate plasma too frequently and put themselves in real danger of being overbled. This problem is particularly acute when the vendor is a chronic alcoholic with borderline liver function. The donor identification system will also help to insure the quality of the product in that vendors will be screened for hepatitis before they receive their identification cards, thus eliminating the hazards involved in handling potentially contaminated plasma.

Defendants' medical experts also expressed concern that a vendor under the influence of alcohol may not have sufficient understanding of the nature of the procedure and the risks it entails. The breathalyzer test requirement is intended to solve this problem. Under the federal regulations, however, Automated Laboratories, Inc. has established reliable procedures to screen out persons under the influence of alcohol at two stages — when they are initially tested by the receptionist and when the physician examines them.

(8) The ordinances in question regulate only plasmapheresis centers that pay vendors. Testimony at trial showed that no whole blood centers in Hillsborough County pay donors. Furthermore, the legislators' concern for the safety of

vendors and the quality of the product is applicable only to paid centers. Medical experts testified that plasma vendors have a much higher incidence of hepatitis than voluntary whole blood donors. Also, the problem of overbleeding does not exist among voluntary whole blood donors who have no monetary incentive to make frequent donations.

Based on the foregoing findings of fact the Court makes the following conclusions of law:

(1) Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder are not preempted by federal regulation. "There is neither such actual conflict between the two schemes of regulation that both cannot stand in the same area, nor evidence of a congressional design to preempt the field." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 141 (1963). Plaintiff pointed to language in the Federal Register expressing the purpose of the federal regulations "to assure uniform adherence to the highest attainable standards of of practice in blood banking, including plasmapheresis and plasma fractionation," 39 Fed.Reg. 18614 (1974); but there is no evidence of express congressional intent to occupy the entire field of assuring high standards of practice in plasmapheresis. Moreover, the comprehensive nature of the federal legislation alone does not imply a congressional intent to preempt. *New York State Dep't. of Social Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Finally, Hillsborough County Ordinances 80-11 and 80-12 supplement rather than conflict with the federal regulations, particularly in the ordinances' emphasis on ensuring vendor safety.

(2) Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder do not deprive Plaintiff of equal protection of the laws. Although the local legislation applies only to paid plasmapheresis centers and not to voluntary whole blood centers, Defendants successfully demonstrated that there is a rational basis for regulating only the paid plasma centers. Because Plaintiff contends that the ordinances deprive Plaintiff of a property right rather than infringe upon a fundamental personal right, a rational basis for enactment of the statute is sufficient. *New Orleans v. Dukes*, 427 U.S. 297 (1976). This rational basis is evident from the following: vendors tend to sell their plasma more frequently than volunteers donate their whole blood; plasma vendors have a much higher rate of hepatitis than whole blood donors; and no paid whole blood centers exist in Hillsborough County.

(3) Hillsborough County Ordinance 80-11 and the rules and regulations promulgated thereunder do not place an impermissible burden on interstate commerce. Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 impermissibly burden interstate commerce. The remainder of Hillsborough County Ordinance 80-12 and the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 do not place an impermissible burden on interstate commerce.

The Supreme Court has stated the general rule for determining whether a state or local law is invalid by virtue of its effect on interstate commerce:

> Where the statute regulates evenhandedly to effect a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to putative public benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

For reasons previously stated, the Court finds that the ordinances regulate evenhandedly and serve a legitimate local purpose. The Court must therefore determine whether the burden, if any, imposed on interstate commerce is clearly excessive in relation to local benefits.

The Plaintiff was unable to demonstrate the total economic impact on it of enforcement of the ordinances. The evidence demonstrated, however, that significant protection for vendors would be assured by the vendor identification system, that the hepatitis pre-test requirement will help insure the quality of the product, and that the license and plasmapheresis fees will pay for the cost to the County of implementing and enforcing the ordinances. Clearly, all of these provisions, which will create some economic burden on the Plaintiff, will significantly benefit the health, safety, and welfare of the citizens of Hillsborough County.

The benefits of the breathalyzer requirement are not so readily apparent, however. Plaintiff demonstrated that the procedures it follows under the federal regulations achieved the same purpose as a breathalyzer test though the subjective evaluation of each potential vendor by the Plaintiff's personnel and physicians. Defendants did not demonstrate that the breathalyzer requirement, which will create a large, albeit precisely undedetermined, economic burden on the Plaintiff, will "effectuate a legitimate public interest" that is not already achieved by Plaintiff's requirement with the federal regulations. Therefore, Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 are invalid in that they impose an impermissible burden on interstate commerce.

Judgment will be entered in accordance with this Opinion.

DATED at Tampa, Florida this 1st day of November, 1982.

WILLIAM J. CASTAGNA
UNITED STATES DISTRICT JUDGE

Copies to:

Counsel of Record

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 81-1161-Civ-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiffs,
vs.
HILLSBOROUGH COUNTY, FLORIDA, et al.,
Defendants.

FILED CLERK, U.S. DISTRICT COURT
NOV. 1, 1982
MIDDLE DISTRICT OF FLORIDA, TAMPA, FLORIDA

FINAL JUDGMENT

In accordance with the Opinion filed herein this date, it is

ADJUDGED:

Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 are invalid in that they impose an impermissible burden on interstate commerce and the Defendants and their agents and employees are hereby enjoined from enforcing or attempting to enforce them.

As to the other claims of Plaintiff Automated Medical Laboratories, Inc., Judgment is entered in favor of the Defendants Hillsborough County, Florida and Hillsborough County Health Department, and Plaintiff shall take nothing.

DATED at Tampa, Florida this 1st day of November, 1982.

WILLIAM J. CASTAGNA
UNITED STATES DISTRICT JUDGE

Copies to:

Counsel of Record

United States Court of Appeals
FOR THE ELEVENTH CIRCUIT

NO. 83-3014

D.C. Docket No. 81-1161-WC
AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,

versus
HILLSBOROUGH COUNTY, FLORIDA, and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

Appeal from the United States District Court for the
Middle District of Florida

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

J U D G M E N T

This cause came on to be heard on the transcript of the record from the United States District Court for the Middle District of Florida, and was argued by counsel;

ON CONSIDERATION WHEREOF, it is now here ordered and holding adjudged by this Court that the judgment of the District Court finding Section 7 of Ordinance 80-12 and § 4 of the rules and regulations invalid is AFFIRMED; the judgment finding the remaining sections of County Ordinances 80-11 and 80-12 and implementing rules and regulations valid is REVERSED;

It is further ordered that defendants-appellees pay to plaintiff-appellant, the costs on appeal to be taxed by the Clerk of this Court.

ISSUED AS MANDATE: MAR 8- 1984

Entered: January 16, 1984
For the Court: Spencer D. Mercer, Clerk
BY: _____
Deputy Clerk

PETITION FOR REHEARING BY PANEL

EMELINE C. ACTON
DOLORES D. MENENDEZ
Assistant County Attorneys
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Telephone: (813) 272-5670

ARGUMENT

Petitioner respectfully requests a rehearing by this court on the issue of whether the challenged local legislation is preempted by the federal regulations concerning plasma. In support of this request, Petitioner asserts that this preemption issue was initially raised in the *amicus* brief. Petitioner was unable to respond to this new issue raised in the *amicus* brief because Petitioner's/Appellee's Answer had already been filed. Moreover, Petitioner had specificially requested the opportunity to respond to the new issues raised by the *amicus* brief in its Motion for Rehearing or Clarification filed July 8, 1983. That opportunity to respond was denied by the court in its Order filed on August 1, 1983, even though Fed. R. App. P. 29 provides as follows: "Save as all parties otherwise consent, any *amicus* brief will support *unless the Court for cause shown shall grant leave for later filing, in which event it shall specify within what period an opposing party may answer*". (Emphasis supplied.)

Because the court's opinion of January 16, 1984 strikes down the local legislation solely on the grounds that the federal government had implicitly preempted the field of plasma regulation, petitioner respectfully requests a rehearing so that the court may re-examine its opinion with full knowledge of evidence and argument on this issue.

The court held that the local legislation was preempted by the federal plasma regulations despite the absence of an express intent to preempt and despite the fact that preemption cannot be presumed in the absence of such a provision. *New York State Dept. of Social Services v. Dublino*, 413 U.S. 405 (1973). Where no express preemption or conflict exists, state and federal legislation must be examined to determine whether they can coexist. Federal and local enactments should as a rule be accommodated and the law does not favor the outster of local legislation. *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Ware*, 414 U.S. 117 (1973). Despite this general rule, the court struck down this local legislation and effectively barred local regulation in this field.

Moreover, the court based its decision on the holding in *Pennsylvania v. Nelson*, 350 U.S. 497 (1956), in which the Supreme Court ruled that the area of sedition legislation had been implicitly preempted by the federal government. In applying the Nelson rationale to the facts in the instant case, however, the court overlooked the fact that sedition has long been recognized as a subject of peculiarly national concern. In fact, the *Nelson* court noted that acts of sedition are acts that are contrary to the interests of the United States and threaten the national security. Furthermore, the court emphasized that the President of the United States had specifically instructed all law enforcement personnel to turn over to the Federal Bureau of Investigation any information in their possession relating to seditious acts. The court also drew attention to the fact that

other federal officials had similarly spoken to the necessity for exclusively federal control of seditious acts against the United States.

On the other hand, the area of public health has long been recognized by the courts as one of particularly local concern.[1] As opposed to the federal officials in the *Nelson* case who spoke out in favor of solely federal control, the Food and Drug Administration stated that it was "pleased to cooperate with Hillsborough County in matters directed at improving consumer protection" and gave consent for Edward R. Atkins, Director of Compliance for the State of Florida, and Herbert M. Smith, Resident in Charge, Tampa Resident Post, to testify on behalf of the local legislation. In regard to the protections supplied by the local legislation which the federal regulations did not cover, Mr. Atkins and Mr. Smith specifically testified that any additional inspection of the plasma firms would be helpful and that such local enforcement would create no difficulties for Mr. Atkins' office in carrying out its duties of regulating plasma centers. (TR 215-216, 223-225)

Furthermore, although the court quotes on page 1251 of its opinion from the Commissioner of Food and Drugs who established a comprehensive National Blood Policy based upon the findings of a special Task Force in Blood Banking, the court overlooks the testimony of Drs. Schmidt and Coleman who were members of that same Task Force on Blood Banking which had advised the federal government on appropriate regulations in this field. (TR 179-180, 200) They testified that the Task Force's recommendation of a uniform vendor registration system for use among several different centers in an area in order to protect the health of vendors had not been incorporated into the federal regulations but was included in the local legislation. (TR 183, 198-200) This evidence that the federal plasma regulations do not encompass all possible areas for the protection of the public health supports the Petitioner's contention that the Commissioner's call for "uniform adherence to the highest attainable standards" was not an announcement of preemption.

[1]Local legislation which seeks to protect the physical health and safety of those persons within its territory is "most impervious to preemption." A Framework for Preemption Analysis, 88 *Yale L.J.* 363, 374 (1978). Thus, the Supreme Court has upheld: 1) local legislation that imposed a requirement that a national agency had refused to impose, *Maurer v. Hamilton*, 309 U.S. 598 (1940), 2) state regulation of the same action regulated by a national agency but for the violation of which the state imposed higher penalties, *California v. Zook*, 336 U.S. 725 (1949), 3) a municipal ordinance regulating a local health concern caused by steam vessels which were already in compliance with comprehensive federal regulations, *Huron Portland Cement Co. v. City of Detroit, Michigan*, 363 U.S. 440 (1960) and 4) state regulation prohibiting the transportation or sale of certain avocados within California which avocados were already marketable under stringent federal standards, *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963).

Rather, the Commissioner was calling for the highest standards which the federal government was able to effectively enforce. These federal standards constitute a minimum level of public health protection beyond which local governments may impose additional reasonable standards. This is particularly true in regard to the challenged local legislation in that this legislation sought to protect aspects of the public health not covered by the federal regulations such as excessive bleeding through visits to different plasma centers, subjective tests of intoxication of prospective vendors performed by employees who benefit depending upon their findings, and exposure in centers to hepatitis positive vendors. Thus, although the court on page 1251 of its opinion distinguishes the local legislation which was upheld in *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. 1981) (Unit B), the federal requirements in both the *Smith* case and the instant case do not regulate every aspect of those areas and leave room for the local legislation to fill out the scheme.

The court's decisive reliance on *Pennsylvania v. Nelson* was misplaced. Rather, the court should have applied the principle enunciated by the United States Supreme Court in the landmark case of *Florida Lime* at 142 that "Federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons — either that the nature of the regulated subject matter permits no other conclusion or that the Congress has inmistakenly so ordained." Although plasma is an admittedly important product, the regulation of the plasma industry is a commercial regulation as opposed to regulation for the national security and federal preemption should not be imposed absent persuasive reasons.

Based on the foregoing argument, Petitioner respectfully requests that this court rehear its decision in this case.

Respectfully submitted this 3rd day of February, 1984.

EMELINE C. ACTON

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that copies of the foregoing Petition for Rehearing has been furnished by U.S. Mail this 3rd day of February, 1984 to: Richard Landfield, Attorney for American Blood Resources Association and Florida Association for Plasmapheresis Establishments, 1220 Nineteenth Street, N.W., Suite 205, Washington, D.C. 20036, and Larry A. Stumpf, Attorney for Automated, Goldstein, Goldman, Kessler & Underberg, 2606 New Work Tower, 100 North Biscayne Boulevard, Miami, Florida 33132.

EMELINE C. ACTON

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
FILED
FEB 23 1984
Spencer D. Mercer
Clerk

NO. 83-3014

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,

versus

HILLSBOROUGH COUNTY, FLORIDA, and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

Appeal from the United States District Court for the
Middle District of Florida

ON PETITION FOR REHEARING

(FEB 23 1984)

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

PER CURIAM:

IT IS ORDERED that the petition for rehearing filed in the above entitled and numbered cause be and the same is hereby denied.

ENTERED FOR THE COURT:

United States Circuit Judge

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
FILED
APR 20 1984
Spencer D. Mercer
Clerk

AUTOMATED MEDICAL LABORATORIES, INC., :
Plaintiff-Appellant, :
-vs- : CASE NO. 83-3014
HILLSBOROUGH COUNTY, FLORIDA, and :
HILLSBOROUGH COUNTY HEALTH DEPARTMENT, :
Defendants-Appellees. :

NOTICE OF APPEAL

Appellant, HILLSBOROUGH COUNTY, FLORIDA, appeals from the Order entered on February 23, 1984 by the United States Court of Appeals, Eleventh Circuit, which denie a rehearing of its decision holding that the federal government had preempted the area of plasma legislation and therefore striking down the ordina es and regulations enacted by HILLSBOROUGH COUNTY to regulate the collection of plasma. This appeal to the United States Supreme Court is taken pursuant to 28 *U.S.C.* §1254(2).

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CERTIFICATE OF SERVICE

All parties required to be served have been served by depositing on this 19th day of April, 1984 copies of this document in a U.S. Post Office, with first class postage prepaid, addressed to counsel of record at his or her post office address as follows:

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EMELIN C. ACTON
DOLORES D. MENENDEZ

DOUGLAS R. GARDNER

MLZ
11/26/80

ORDINANCE #80-11

AN ORDINANCE AMENDING THE HILLSBOROUGH COUNTY OCCUPATIONAL LICENSE ORDINANCE #80-6; PROVIDING A SPECIFIC CLASSIFICATION FOR BLOOD PLASMA DONOR CENTERS AND SETTING THE OCCUPATIONAL LICENSE TAX AT $225.00; PROVIDING FOR A PERMIT, AND PROVIDING AN EFFECTIVE DATE

Section 1. Hillsborough County Ordinance 80-6 is amended to add Section 56.01 to read as follows:

Section 56.01 BLOOD PLASMA DONOR CENTERS

(1) Every person or association of persons conducting, carrying on or otherwise engaging in the business (occupation) of a Blood Plasma Donor Center as defined below, shall pay a license tax of $225.00.

(2) "Blood Plasma Donor Center" is defined as any facility, laboratory, or place of business which performs the procedure known as "plasmapheresis" on commercial Blood Plasma Vendors and which compensates said Blood Plasma Vendors by payment of money or other thing of value.

Section 2. Hillsborough County Ordinance 80-6 is amended to add Section 57.01 to read as follows:

Secton 57.01 — BLOOD PLASMA DONOR CENTERS; COUNTY PERMIT REQUIRED; PENALTY —

(1) No license to engage in the occupation of a Blood Plasma Donor Center or any other business entity for which a license is required by Section 56.01 of this Ordinance, shall be issued to any person or association of persons not possessing a valid permit issued by the Hillsborough County Board of County Commissioners (Board). Said permit shall be issued in triplicate with the original being given to the applicant, one copy being retained by the Hillsborough County Health Department, and one copy being retained by the Tax Collector. All permits and licenses issued under the provisions of this Ordinance shall be non-transferable. No permit shall be issued by the Board until the following conditions have been fulfilled:

(a) The applicant for the permit has:

1. Furnished the Hillsborough County Health Department (upon forms provided) with the name and mailing and residential addresses for all non-owner and owner personnel employed with the place of business for which the related license tax is applicable pursuant to Section 56.01 of this Ordinance.

2. Furnished to the Hillsborough County Health

Department (upon forms provided) a list and description of the equipment and facilities of the place of business for which related license tax is applicable pursuant to Section 56.01 of this Ordinance.

3. Furnished to the Hillsborough County Health Department (upon forms provided) such other information as deemed necessary by the Hillsborough County Health Department.

4. Allowed the Hillsborough County Health Department reasonable and continuing access to the premises of the Blood Plasma Donor Center or other business entity concerned with the permit sought by the applicant; said access being granted for purposes of allowing the Hillsborough County Health Department opportunity to inspect the premises.

(2) The possessor of any permit issued by the Board shall, within thirty (30) days of an event or occurrence that causes a change to the information given to the Hillsborough County Health Department pursuant to sub-sections 57.01(1)(a)1, 57.01(1)(a)2, and 57.01(1)(a)3 of this Ordinance, advise the Hillsborough County Health Department (in writing) of such change.

(3) The Hillsborough County Health Department shall, within fifteen (15) days of receiving a completed application for a permit as described by this Section, forward to the Board all such information furnished by the permit applicant; together with the recommendation of the Hillsborough County Health Department and other pertinent information deemed advisable. The Board shall consider the information submitted to it in open, public meeting after notice to the permit applicant and the Hillsborough County Health Department; whereupon the Board shall either issue the permit, continue the matter for just cause, or deny the permit.

(4) Blood Plasma Donor Centers or other business entities issued a permit pursuant to the provisions of this Section shall automatically be re-permitted annually by the Board unless such re-permitting is denied by the Board for just cause after notice and opportunity to be heard. The County Tax Collector shall be notified when re-permitting is denied by the Board.

(5) Every licensee comprehended by Section 56.01 of this Ordinance shall at all times while engaging in the occupation for which licensed, display at the applicable place of business both the license thereby required and the permit required by this Section. Failure or refusal to do so shall be prima facie evidence of engaging in such occupation without a license.

(6) Anyone engaging in any occupation comprehended by

Section 56.01 of this Ordinance without a license and the permit required by this Section or who shall obtain any such permit or license by fraud or deceit shall, be subject to prosecution and punishment as described in Section 7.02 of this Ordinance.

Section 3. This Ordinance shall become effective immediately upon acknowledgement from the Secretary of State that it has been properly filed as required by law.

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, JAMES F. TAYLOR, Clerk of the Circuit Court and Ex Officio Clerk of the Board of County Commissioners of Hillsborough County, Florida, do hereby certify that the above and foregoing is a true and correct copy of an Ordinance adopted by the Board in its regular meeting of November 26, 1980, as the same appears of record in Minute Book 76 of the Public Records of Hillsborough County, Florida.

WITNESS my hand and official seal this 5th day of December, 1980.

JAMES F. TAYLOR, JR., CLERK
BY: _____
Deputy Clerk

FINAL
MLZ
11/26/80

ORDINANCE #80-12

AN ORDINANCE OF HILLSBOROUGH COUNTY, FLORIDA; RELATING TO IDENTIFICATION OF COMMERCIAL BLOOD PLASMA VENDORS: DEFINING TERMS; REQUIRING BLOOD PLASMA VENDOR IDENTIFICATION CARDS; ESTABLISHING PROCEDURES FOR OBTAINING CARDS; PROVIDING FOR RECORD KEEPING AND REPORTING; SETTING FEES; REQUIRING BREATH ANALYSIS; REQUIRING REPORTING OF COMMUNICABLE DISEASE; PROVIDING FOR ADMINISTRATION; PROVIDING FOR ENFORCEMENT AND INSPECTION; REQUIRING NOTICE; SPECIFYING PENALTY FOR VIOLATIONS; PROVIDING FOR SEVERABILITY; PROVIDING AN EFFECTIVE DATE.

WHEREAS, Section 125.01(1)(w), Florida Statutes allows the Board of County Commissioners of Hillsborough County, Florida, to perform any acts not inconsistent with law which are in the common interest of the people of the County, and exercise all powers and privileges not specifically prohibited by law; and

WHEREAS, Section 125.01(1)(t), Florida Statutes allows the Board of County Commissioners of Hillsborough County, Florida to adopt ordinances necessary for the exercise of its power; and

WHEREAS, the Hillsborough County Board of County Commissioners finds and determines that the interests of the public health mandate the monitoring of the plasmapheresis procedure within Hillsborough County; and

WHEREAS, Section 381.311, Florida Statutes requires local health officials to enforce provisions of local ordinance relating to the public health.

NOW, THEREFORE, BE IT ORDAINED BY THE BOARD OF COUNTY COMMISSIONERS OF HILLSBOROUGH COUNTY, FLORIDA, IN REGULAR MEETING ASSEMBLED THIS _____ DAY OF _____, 1980.

Section 1. Short Title — This ordinance shall be known as the "Commercial Blood Plasma Vendor Identification Ordinance".

Section 2. Statement of Purpose — The purpose of this Ordinance is to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest

of the health of the people of Hillsborough County.

Section 3. Definitions

(A) "Commercial Blood Plasma Vendor" is defined as an individual who sells, barters, or exchanges for monetary consideration, the liquid portion of his or her blood (plasma), through the plasmapheresis process.

(B) "Plasmapheresis" is defined as the procedure whereby whole blood is removed from a Commercial Blood Plasma Vendor by venipuncture (or phlebotomy) the plasma is separated therefrom, and the blood cells returned to the Vendor.

(C) "Plasmapheresis Facility" is defined as any facility, laboratory, or place of business where Commercial Blood Plasma Vendors participate in the plasmapheresis process.

(D) "Department" is defined as the Hillsborough County Health Department.

Section 4. Plasma Donor Identification Card. All Commercial Blood Plasma Vendors within Hillsborough County are required to obtain a valid plasma vendor identification card from the Department. The card shall contain identifying information, as required by the Department, and a number, unique to the Vendor. Only one (1) card and one (1) number shall be issued to each Vendor. The identification card shall be good for one (1) plasmapheresis facility only, the name of which shall appear on the face of the identification card.

Section 5. Procedure

(A) Each prospective Commercial Blood Plasma Vendor shall, before undergoing plasmapheresis, make application to the Department, on a form to be provided by the Department, for a plasma vendor identification number and a plasma vendor identification card. The Commercial Blood Plasma Vendor must provide such identifying information as is deemed necessary by the Department and shall tender to the Department a fee of no more than ten dollars ($10.00) which fee shall fairly reflect the Department's costs for issuance of the plasma vendor identification card. Identification cards issued under the provisions of this Ordinance shall be valid for six (6) months from the date of issue.

(B) In the event a plasma vendor identification card is lost, stolen, or mutilated, a duplicate card will be issued, which card shall be valid for the same period as the original card, and shall only be good for the same plasmapheresis facility as the original card. The fee for such duplicate shall be no more than three dollars ($3.00).

Section 6. Record-keeping

(A) No plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a Commercial

Blood Plasma Vendor until said Vendor presents the plasmapheresis facility with a valid plasma Vendor identification card as required by Section 4 of this Ordinance. The plasmapheresis facility shall keep accurate records of each plasmapheresis procedure performed by it, which shall include:

(1) The date of the plasmapheresis procedure;
(2) The name, address, age, weight, height and sex of the Vendor;
(3) The plasma Vendor identification number of the Vendor;
(4) The results of breath analysis of the Vendor as required by Section 7 of this Ordinance;
(5) The amount of whole blood, not including anticoagulant, removed from the Vendor during the plasmapheresis procedure;
(6) The proportion of the blood cells successfully returned to the Vendor at the time of each procedure;
(7) The results of testing for hepatitis;
(8) The current hematocrit value
(9) Any other identifying information as the Department may deem necessary.

(B) All plasmapheresis facilities within Hillsborough County shall provide the aforementioned information daily to the Department, in writing, who shall compile and maintain such information and give prompt notification of any violation of this Ordinance or of the rules and regulations promulgated hereto.

(C) Prior to beginning the plasmapheresis procedure upon any Commercial Blood Plasma Vendor, the plasmapheresis facility shall ascertain that said Vendor has not participated in the plasmapheresis procedure in excess of the amounts listed below within the times indicated:

(1) The amount of whole blood, not including anticoagulant, removed from a Vendor during the plasmapheresis procedure in any forty-eight (48) hour period shall not exceed one thousand (1,000) milliliters unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case the amount of whole blood, not including anticoagulant removed from the Vendor during the plasmapheresis procedure, in any forty-eight (48) hour period shall not exceed one thousand two hundred (1,200) milliliters.

(2) The amount of whole blood, not including anticoagulant, removed from a Vendor during the plasmapheresis procedure, within a seven-day period shall not exceed two thousand (2,000) milliliters, unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case the amount of whole blood, not including anticoagulant, removed from the Vendor during the plasmapheresis procedure, within a seven-day period shall not exceed two thousand four hundred (2,400) milliliters.

(3) During the plasmapheresis procedure, no more than five hundred (500) milliliters of whole blood shall be removed from a Vendor at one time unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case no more than six hundred (600) milliliters of whole blood shall be removed from the Vendor at one time.

(D) No plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a Commercial Blod Plasma Vendor until said Vendor has been examined by a physician and issued a certificate of good health as required by the regulations of the Food and Drug Administration (FDA), of the United States Department of Health and Human Services.

(E) The Department shall keep all records in a manner which protects the rights of individuals to the confidentiality of their medical records. The disclosure of the identity of, or other information relating to Commercial Blood Plasma Vendors is expressly prohibited, except as such disclosure is directly related to and necessary for enforcement of this Ordinance or as is required by law.

(F) The Department shall assess a fee upon each plasmapheresis facility for the purpose of paying the expenses which the Department shall incur, both direct and indirect, in the implementation and maintenance of the Commercial Blood Plasma Vendor Identification System. The fee shall be based upon the number of plasmapheresis procedures performed by the plasmapheresis facility and shall be payable monthly by the facility upon receipt of an invoice from the Department. Said fee shall not exceed the amount of one dollar ($1.00) for each plasmapheresis procedure which has been performed by the facility, and the total of fees collected shall not exceed the cost to the Department of administering and maintaining the Commercial Blood Plasma Vendor identification system.

Section 7. Breath Analysis — It shall be unlawful for any plasmapheresis facility in Hillsborough County to extract whole blood or any of its products from a Commercial Blood Plasma Vendor unless, immediately prior to said extraction, the facility shall analyze the breath of the Commercial Blood Plasma Ven-

dor and determine from such analysis that the blood of the Commercial Blood Plasma Vendor does not contain alcohol in excess of 0.07 per cent, weight per volume. For the purpose of performing the required breath analysis, each plasmapheresis facility in Hillsborough County shall maintain upon the premises thereof such testing materials, equipment, supplies, and personnel as are approved by the Department.

Section 8. Reporting of Communicable Disease — Any plasmapheresis facility or employee thereof who shall discover that the Vendor evidences veneral disease, or other communicable disease shall immediately submit to the Hillsborough County Health Department a confidential report setting forth the nature of the disease and the name, address commercial blood plasma vendor identification number, and other information sufficient to identify and locate the Vendor.

Section 9. Prohibited Acts — It shall be unlawful for any person to obtain or attempt to obtain more than one plasma vendor identification card or more than one plasma vendor identification number, or for any person to attempt to utilize a vendor identification card or vendor identification number of another individual, or for any person to provide false information to a plasmapheresis facility or to the Hillsborough County Health Department in connection with the application for a Vendor identification card or identification number or in connection with any plasmapheresis procedure.

Section 10. Enforcement and Inspection — It shall be the responsibility of the Director of the Hillsborough County Health Department or his duly authorized representative to enforce the provisions of this Ordinance throughout Hillsborough County and the Director may promulgate rules and regulations necessary to carry out the provisions of this Ordinance. The Hillsborough County Health Department may make periodic inspections of each plasmapheresis facility in Hillsborough County for the purpose of determining the existence of any violation of this Ordinance.

Section 11. Denial, Suspension or Revocation of Identification Card.

A. If the Director of the Hillsborough County Health Department determines that an individual has violated a provision of this Ordinance, he may deny, suspend, or revoke any Vendor identification card or identification number, according to the following criteria:

(1) For a violation by a person who is not a registered Commercial Blood Plasma Vendor, a disqualification of that person from becoming a registered Vendor for a period not exceeding ninety (90) days for each violation.

(2) For the first violation by a registered Commercial Blood Plasma Vendor, suspension of the Vendor identification card and number and all the privileges incident thereto for a period not exceeding ninety (90) days.

(3) For the second violation by a registered Commercial Blood Plasma Vendor, suspension of the Vendor identification card and number and all the privileges incident thereto for a period not exceeding one (1) year.

(4) For the third violation by a registered Commercial Blood Plasma Vendor, suspension of the Donor identification card and number and all the privileges incident thereto for a period not exceeding five (5) years, or permanent revocation of the Vendor identification card and registration number and all the privileges incident thereto.

(B) If the Director of the Hillsborough County Health Department or his designee shall determine that a violation of this Ordinance or of any regulation promulgated hereunder has occurred, the Director may take one or more of the following actions:

(1) Service upon the person or facility in violation of a citation setting forth the violation and establishing a time within which such violation must be corrected.

(2) Initiation of a procedure for the denial, revocation, suspension, limitation, of any Commercial Blood Plasma Vendor identification card.

(3) The initiation of a judicial procedure for injunctive action against any individual or organization violating this ordinance, it being hereby declared that the performance of the plasmapheresis procedure on any Commercial Blood Plasma Vendor in violation of this Ordinance or any regulation promulgated hereunder is a nuisance inimical to the public health, welfare, and safety.

(4) Whenever the Director of the Department shall have determined the existence of a violation of this Ordinance which constitutes an immediate threat to the health, safety, or welfare of a Commercial Blood Plasma Vendor, a potential recipient of blood or plasma, or the public, and such condition cannot or will not be immediately corrected, the Director of Public Health may order the immediate closing of such plasmapheresis facility and initiate judicial proceedings seeking injunctive relief to accomplish said purpose until such time as the threat is found no longer to exist.

(C) Whenever the Director of the Hillsborough County Health Department or his duly authorized representative believes that there has been a violation of the provisions of this Ordinance, he shall serve notice of such violation in writing to the party responsible for such violation. The notice shall specify the violation and shall be deemed to be properly served and binding upon the party responsible, if a copy is served personally or served by certified mail, or if after diligent search and inquiry the party responsible for the violation cannot be found or served by personal service or certified mail, a copy of the notice is published once during each week for four (4) consecutive weeks in a newspaper of general circulation within Hillsborough County. The newspaper shall meet such requirements as prescribed by law for such purpose. Such notice shall inform the party to whom it is directed of the right to apply to the Hillsborough County Board of County Commissioners for a hearing and review of the matters specified in the notice.

Section 13. Appeal — Any person aggrieved by a decision of the Department made under the provisions of this Ordinance shall have the right to appeal such decision to the Hillsborough County Board of County Commissioners (Board). Said appeal must be in writing and received by the Board no later than ten (10) days from the date of the decision to be reviewed. The Board shall set such appeal for hearing at the earliest possible date, and cause notice thereof to be given to the appellant and the Director of the Hillsborough County Heatlh Department. The Board shall hear and consider all facts material to the appeal and render a decision promptly. The Board may affirm, reverse, or modify the action or decision appealed from providing that the Board shall not take any action which conflicts or nullifies any of the provisions of this Ordinance. The Board shall specifically state in its decision the date by which compliance must be made. The decision of the Board shall be final, and no rehearing or reconsideration shall be considered. Any party aggrieved by any decision of the Board on appeal taken to it, may apply to the Circuit Court of Hillsborough County for a review by writ of certiorari in accordance with the applicable Florida appellate rules.

Section 14. Penalty — A conviction for violation of the provisions of this Ordinance shall be punishable by a fine not to exceed five hundred dollars ($500.00) or by imprisonment in the County jail for a term not to exceed sixty (60) days or both such fine and imprisonment, as provided in Section 125.69, Florida Statutes.

Section 15. Federal Regulations — The regulations of the

Commissioner of the Food and Drug Administration of the United States Department of Health and Human Services, as they may be amended from time to time concerning plasmapheresis and source plasma (human) currently appearing at 21 CFR Part 640, Subpart G, Section 640.60 et seq, are here incorporated by reference and shall be a part of this Ordinance as though set forth herein verbatim.

Section 16. Severability — If any section, subsection, sentence, clause, provision or part of this Ordinance shall be held invalid for any reason, the remainder of this Ordinance shall not be affected thereby, but shall remain in full force and effect.

Section 17. Effective Date — This Ordinance shall take effect ninety (90) days after filing with the Secretary of State as provided by law.

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, JAMES F. TAYLOR, Clerk of the Circuit Court and Ex Officio Clerk of the Board of County Commissioners of Hillsborough County, Florida, do hereby certify that the above and foregoing is a true and correct copy of an Ordinance adopted by the Board in its regular meeting of November 26, 1980, as the same appears of record in Minute Book 76 of the Public Records of Hillsborough County, Florida.

WITNESS my hand and official seat this 5th day of December, 1980.

JAMES F. TAYLOR, JR. CLERK
BY: _____
Deputy Clerk

3/5/81

RULES AND REGULATIONS PURSUANT TO HILLSBOROUGH COUNTY ORDINANCE #80-12

Section 1. — Purpose

These Rules and Regulations are adopted to establish procedures for the monitoring of the plasmapheresis process within Hillsborough County, and the issuance of Commercial Blood Plasma Vendor Identification Cards by the Hillsborough County Health Department, under the Authority of Hillsborough County Ordinance 80-12.

Section 2. — Identification

Before being issued a Commercial Blood Plasma Vendor Identification Card pursuant to Hillsborough County Ordinance 80-12, each applicant shall furnish to the Hillsborough County Health Department:

A. One of the following items of positive identification:
1. A Social Security card exhibiting the applicant's signature;
2. A Hillsborough County voter registration card exhibiting the applicant's signature;
3. A selective service identification card exhibiting the applicant's signature;
4. A valid driver's license exhibiting the applicant's photograph and signature;
5. A United States passport exhibiting the applicant's photograph and signature;
6. Discharge documents from the United States military service exhibiting the applicant's signature.

B. A Certificate of Good Health as required by the regulations of the Food and Drug Administration (F.D.A.) of the United States Department of Health and Human Services and Hillsborough County Ordinance 80-12.

C. An Affidavit, signed by the applicant and notarized, stating that said applicant has not been detained or treated for acute or chronic alcoholism during the preceding twelve months.

Section 3 — Fees

As required by Hillsborough County Ordinance 80-12

A. The fee for issuance of the Commercial Blood Plasma Vendor Identification Card shall be two dollars ($2.00) to be paid by the applicant.

B. The fee for issuance of a duplicate Commercial Blood Plasma Vendor Identification Card, under the provisions of Section 5(B) of Hillsborough County Ordinance 80-12, shall be two dollars ($2.00), to be paid to the applicant.

C. The fee for administration and maintenance of the Commercial Blood Plasma Vendor Identification system under the provisions of Hillsborough County Ordinance 80-12, shall be the sum of one dollar ($1.00), for each plasmapheresis procedure performed, to be paid by the plasmapheresis facility.

Section 4 — Breath Analysis

Alcohol level testing as required by Section 7 of Hillsborough County Ordinance 80-12, shall be performed by a qualified operator using a model 900 Smith and Wesson breath analyzer or equipment of equal quality.

Section 5 — Inspections

Pursuant to Section 10 of Hillsborough County Ordinance 80-12, duly authorized representatives of the Director of Hillsborough County Health Department will inspect each plasmapheresis facility within Hillsborough County not less than once annually. These inspections will be made without prior notice to the plasmapheresis facility. Such inspection shall include records required to be kept by the plasmapheresis facility under Hillsborough County Ordinance 80-12.

Section 6 — Additional Tests

In the event it is deemed necessary by a physician in the interests of the public health, the Hillsborough County Health Department may require specific tests in addition to those reported and/or an independent physical examination by a physician other than the physician issuing the applicant's Certificate of Good Health.

The Hillsborough County Health Department may delay issue of the Commercial Blood Plasma Vendor Identification Card for a period of ten (10) days if deemed necessary for examination testing, or investigative purposes.

Section 7 — Phase-In Period

As of the effective date of Hillsborough County Ordinance 80-12, no plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a commercial blood plasma vendor until said vendor presents the plasmapheresis facility with a valid Commercial Blood Plasma Vendor Identification Card; provided however, during the period of ninety (90) days from the date these Rules and Regulations are adopted, each plasmapheresis facility may, nevertheless, perform the

plasmapheresis procedure on a non card holder in instance where such commercial blood plasma vendors are vendors who have previously and regularly undergone the plasmapheresis procedure at that particular facility and where such vendors appear on that facility record of current vendors as of the effective date of Hillsborough County Ordinance 80-12.

Section 8 — Falsification of Information

In the case of falsification by a commercial blood plasma vendor of any information required by Hillsborough County Ordinance 80-12, or these Rules and Regulations promulgated pursuant thereto, the Hillsborough County Health department may deny the issuance of or revoke any existing Commercial Blood Plasma Vendor Identification Card of the person falsifying any information.

CERTIFICATION

This is to certify that the foregoing Rules and Regulations were promulgated pursuant to Section 10 of Hillsborough County Ordinance 80-12.

DONALD S. KWALECK, M.D.
Director of Hillsborough
County Health Department

In The
UNITED STATES COURT OF APPEALS
For the Eleventh Circuit

Case No. 83-3014

AUTOMATED MEDICAL LABORATORIES, INC.
Plaintiff-Appellant,

vs.

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

MOTION FOR RECONSIDERATION OR
CLARIFICATION

EMELINE C. ACTON
DOLORES D. MENENDEZ
Assistant County Attorneys
Hillsborough County, Florida
Post Office Box 1110
Tampa, Florida 33601
Telephone: (813) 272-5670

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

AUTOMATED MEDICAL LABORATORIES, INC. Plaintiff-Appellant, -vs- HILLSBOROUGH COUNTY, FLORIDA AND HILLSBOROUGH COUNTY HEALTH DEPARTMENT, Defendants-Appellees.	CASE NO. 83-3014

MOTION FOR RECONSIDERATION OR
CLARIFICATION

COMES NOW Appellee HILLSBOROUGH COUNTY and requests that this Honorable Court reconsider the Motion of the American Blood Resources Association (ABRA) and Florida As-

sociation of Plasmapheresis Establishments (FAPE) For Leave To File A Brief As *Amicus Curiae* or clarify the Order entered by this Honorable Court on June 28, 1983 granting said Motion and as grounds therefor states as follows:

1. Fed. R. App. P. 29 provides that "Save as all parties otherwise consent, any *amicus curiae* shall file its brief within the time allowed the party whose position as to affirmance or reversal the *amicus* brief will support *unless the Court for cause shown shall grant leave for later filing, in which event it shall specify within what period an opposing party may answer*". (Emphasis supplied.)

2. On or about June 17, 1983, counsel for ABRA and FAPE filed with this Court a Motion For Leave To File Brief As *Amicus Curiae* and a Memorandum In Support of that Motion.

3. In that Motion For Leave To File Brief As *Amicus Curiae*, counsel for ABRA and FAPE represented that "counsel for Hillsborough County, Florida has indicated on behalf of Hillsborough County, Florida and Hillsborough County Health Department, Defendants-Appellees, that they will npt oppose this Motion provided that the *amicus* brief be filed within a time frame so as not to delay unduly the Court's consideration of this appeal and provided that the Defendants-Appellees have a reasonable opportunity to respond to the *amicus* brief".

4. Counsel for Hillsborough County did not consent on behalf of the County or the Health Department to the filing of an *amicus* brief by counsel for ABRA and FAPE although counsel for ABRA and FAPE has maintained otherwise. [See attached letters.]

5. Counsel for Hillsborough County was told by Brenda Hauck, Deputy Clerk, that the County would be receiving a request from the Court for any opposition or comments in response to the Motion.

6. Counsel for the County is aware of Fed. R. App. P. 27(a) wherein it states that a response in opposition to a motion may be filed within seven days after service of the motion; however, counsel was awaiting the letter which the Clerk's office had said was mailed before responding, but which counsel for Hillsborough County has never received.

7. This Court entered an Order dated June 28, 1983 granting the Motion For Leave To File Brief *Amicus Curiae*. Counsel for the County received a copy of said Order on July 1, 1983. That Order failed to specify the time period within which the County must file its responsive brief in accordance with Fed. R. App. P. 29.

8. Moreover, the County does, in fact, oppose the Motion which was filed some two weeks after the submission to the

Court of the final brief in this appeal and which seeks not only to inject new issues into this appeal, but also to present new evidence to the Court which was not before Judge Castagna at trial.

9. The County also opposes the Motion on the grounds that it will result in a delay in the resolution of this matter. Such a delay is particularly objectionable in that the County has voluntarily refrained from enforcing Hillsborough County Ordinances Nos. 80-11 and 80-12 and the Rules and Regulations promulgated thereunder pending a resolution of this matter despite the County's great interest in regulating this area for the protection of the public safety.

WHEREFORE, the County requests that this Court reconsider the Motion For Leave To File Brief as *Amicus Curiae* filed by counsel for ABRA and FAPE together with this Motion and deny the Motion For Leave To File *Amicus;* alternatively, if this Court refuses the County's request to reconsider the Motion For Leave To File *Amicus*, the County requests that the Court issue an Order specifying the time period within which the County must file a responsive brief.

9. The County also opposes the Motion on the grounds that it will result in a delay in the resolution of this matter. Such a delay is particularly objectionable in that the County has voluntarily refrained from enforcing Hillsborough County Ordinances Nos. 80-11 and 80-12 and the Rules and Regulations promulgated thereunder pending a resolution of this matter despite the County's great interest in regulating this area for the protection of the public safety.

WHEREFORE, the County requests that this Court reconsider the Motion For Leave To File Brief as *Amicus Curiae* filed by counsel for ABRA and FAPE together with this Motion and deny the Motion For Leave To File *Amicus;* alternatively, if this Court refuses the County's request to reconsider the Motion For Leave To File *Amicus*, the County requests that the Court issue an Order specifying the time period within which the County must file a responsive brief.

Respectfully submitted,

EMELINE C. ACTON
DOLORES D. MENENDEZ
Attorneys for Hillsborough County, Florida
Post Office Box 1110
Tampa, Florida 33601
(813) 272-5670

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing Motion for Reconsideration or Clarification has been furnished by U.S. Mail this 7th day of July, 1983 to: Richard Landfield, Attorney for American Blood Resources Association and Florida Association of Plasmapheresis Establishments, 1220 Nineteenth Street, N.W., Suite 205, Washington, D.C. 20036, and Larry A. Stumpf, Attorney for Automated, Goldstein, Goldman, Kessler & Underberg, 2606 New World Tower, 100 North Biscayne Boulevard, Miami, Florida 33132.

EMELINE C. ACTON

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 83-3014

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,

versus

HILLSBOROUGH COUNTY, FLORIDA, and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

Appeal from the United States District Court for the
Middle District of Florida

Before TJOFLAT, VANCE and HENDERSON, Circuit Judges.

BY THE COURT:

IT IS ORDERED THAT the motion of appellee Hillsborough County for reconsideration or clarification of this court's order granting the American Blood Resources Association and Florida Association of Plasmapheresis Establishments leave to file a brief as amici curiae is denied.

MOT-6H
(Rev. 5/82)